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09/776,787

CASE VA/H-33198



FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

EU52461449US  
Express Mail Label NumberJanuary 10, 2006  
Date of Deposit

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE

KNAPE ET AL.

PATENT NO: 6,974,577

FILED: FEBRUARY 4, 2003

ISSUED: DECEMBER 13, 2005

FOR: INACTIVATED BOVINE SCOURS VACCINES, PROCESS AND  
METHOD OF PREVENTING BOVINE SCOURSCommissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450REQUEST FOR RECONSIDERATION  
OF PATENT TERM ADJUSTMENT

Sir:

The Office issued U.S. Patent 6,974,577 on December 13, 2005. The Office calculated the Patent Term Adjustment under 35 U.S.C. § 154(b) to be 575 days. The undersigned believes that the Office's calculation to be incorrect and that the correct Patent Term Adjustment is 664 days.

37 C.F.R. § 1.705(d) states that any Request for Reconsideration of Patent Term Adjustment must be filed within two months of the issuance of a patent. This Request for Reconsideration of Patent Term Adjustment is being filed on the date indicated above which is on or before February 13, 2006. As such, this Request for Reconsideration of Patent Term Adjustment is considered timely filed.

When the Office issued the Notice of Allowance and the Office's initial calculation of the PTA, the undersigned believed that the Office awarded to Novartis too many days. The undersigned felt that the Office incorrectly calculated the PTA by not deducting a certain number of days because of Novartis' delay.

01/13/2006 MAHME2 00000116 190134 6974577

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200.00 DA

In order to comply with the undersigned's duty of candor, the undersigned attempted to notify the Office of its mistake. Because the undersigned was not requesting additional time but rather a reduction in the PTA, the undersigned sent a "Letter Regarding Shortening Of Patent Term Adjustment" to the Office to point out the error and to try to correct it. A copy of this "Letter" is attached. This "Letter" was submitted on August 1, 2005.

Yet, in calculating the final PTA, the USPTO incorrectly deducted 120 days for the submission of this "Letter". This "Letter" did not qualify as any document which would count as a delay by Novartis for which the 120 day deduction was taken.

Enclosed is a document which sets out correctly the events, the deadlines, and if there were delays on either Novartis' side or the USPTO's side, and the number of days of the delay.

This document indicates that the USPTO delayed 449 days after the 14 month deadline for sending out the first substantive Office Action, delayed 234 days for sending out the Notice of Allowance, and delayed 12 days for issuing the patent. The USPTO delayed a total of 695 days.

The document indicates that Novartis delayed in responding to the non-substantive first Office Action. This was Novartis' only delay. The submission of the "Letter" on August 1, 2005, to correct the PTA does not qualify as a delay by Novartis. Yet the Office deducted 120 days from Novartis' time as a result of this letter.

695 days (USPTO delays) – 31 days (Novartis delays) = 664 days.


**As such, Novartis should receive an additional 664 days for the PTA.**

This patent is not subject to a terminal disclaimer. There were no circumstances during the prosecution of the application which constitutes a failure to engage in reasonable efforts to conclude processing or examination of the application as set forth in 37 C.F.R. § 1.704.

This Request is being accompanied by the fee set forth in 37 C.F.R. § 1.18(e) which is \$ 200.00 which the Commissioner is authorized to charge to Deposit Account 19-0134.

Respectfully submitted,

Novartis  
Corporate Intellectual Property  
One Health Plaza, Building 104  
East Hanover, NJ 07936-1080  
(862) 778-7922

  
David L. Marks  
Attorney for Applicants  
Reg. No. 37,881

Date: January 10, 2006



Case No. H-33198

Appln. No. 09/776,787

### Patent Term Adjustment Chart

Event Description	Date of Event	Time Allowance	Met Time Frame? (Yes or No)		Adjustment - No. of Days	
			PTO	Novartis	PTO (+)	Novartis (-)
U.S. filing (after 5/28/00)	2/4/01	-----				
Non-Substantive First OA	4/30/01	-----				
Response to OA	8/30/01	3 months from OA		No		31
First OA	6/27/03	14 months from filing date	No		449	
Response to OA	8/26/03	3 months from OA		Yes		
Subsequent OA	10/1/03	4 mo. from Response	Yes			
Response to OA	12/15/03	3 months from OA	Yes			
Subsequent OA <i>Allowance</i>	3/24/04	4 mo. from Response	Yes			
Response to OA <i>RCE</i>	6/15/04	3 months from OA		Yes		
Subsequent OA		4 mo. from Response				
Response to OA		3 months from OA				
Notice of Allowance	6/6/05	4 mo. from Response or 14 mos. from filing date if <u>first</u> substantive action	No		234	
(Drawings/312 Amendment/ Resp. to Examiners Reasons for Allowance/etc.)		See Footnote Below *				
Response from PTO (for 312 Amendment/Drawings/etc.)		See Footnote Below *				
Issue Fee Paid	8/1/05	3 months from NOA		Yes		
Issued	12/13/06	4 mo. from Issue Fee Paid	No		12	
		3 years from filing date**	N/A		***	***

#### "Initial" PTA

PTO Deficient =	+ 683 days
Novartis Deficient =	- 31 days
Initial Adjustment =	652 days

#### "Final" PTA

PTO Deficient =	+ 695 days
Novartis Deficient =	- 31 days
Final Adjustment =	664 days

\* PTA PENALTY FOR FILING AFTER THE NOTICE OF ALLOWANCE: **Drawings:** 4 months (120 days) from date of their filing (even if requested by the Examiner) unless a response is received from the PTO; **312 Amendments:** penalty starts on the date the amendment is mailed and ends on the date of the Office Action/Notice in response or 4 months (120 days) whichever is shorter; **Response to Examiner's Reasons for Allowance and Request for PTA** no reduction/penalty of time.

\*\* This calculation does not apply to applications with RCE's as they are not required to issue within 3 years. All other PTA/PTE calculations are not affected.

\*\*\* No Overlap allowed - We get the greater of the 2 possibilities.



FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10	
EV524614293US	August 1, 2005
Express Mail Label Number	Date of Deposit

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

KNAPE ET AL.

APPLICATION NO: 09/776,787

FILED: FEBRUARY 4, 2001

FOR: INACTIVATED BOVINE SCOURS VACCINES, PROCESS AND  
METHOD OF PREVENTING BOVINE SCOURSCommissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450LETTER REGARDING SHORTENING OF PATENT TERM ADJUSTMENT

Sir:

The Office issued a Notice of Allowance for the above referenced patent application on June 6, 2005. The Office determined that the Patent Term Adjustment under 35 U.S.C. § 154(b) is 683 days. The undersigned believes that the correct Patent Term Adjustment is 652 days.

MPEP § 2733 states in part:

If a registered practitioner receives a notice of allowance with a patent term adjustment that is longer than expected, the practitioner should disclose the error to the Office in compliance with the practitioner's duty of candor and good faith in practice before the Office. Where the correct patent term adjustment is thought to be less than indicated by the Office, an application for term adjustment under 37 C.F.R. § 1.705(b) need not be filed. Instead, a letter could be filed with the issue fee payment, indicating that the term adjustment is thought to be longer than appropriate.

As such, please accept this letter in fulfillment of MPEP § 2733 because the undersigned believes that the USPTO incorrectly gave the Applicants too many days for the Patent Term Adjustment. Enclosed is a sheet indicating the undersigned's calculations. In short, the Office


did not deduct 31 days from the Applicants because of Applicants' delay in submitting a signed Declaration and Power of Attorney. The Notice of Missing Parts issued on April 30, 2001. Applicants had until July 30, 2001 to submit the Declaration and Power of Attorney without being deducted days for delay. Instead, Applicants submitted the Declaration and Power of Attorney on August 30, 2001, thirty-one (31) days late.

The USPTO delays were a total of 683 days. When one subtracts the Applicants delay of 31 days, one gets a Patent Term Adjustment of **652 days** owed to the Applicants.

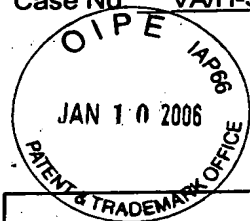
It is the undersigned's understanding that under MPEP § 2733 no fee is required. It is noted that this Letter is being filed concurrently with the payment of the Issue Fee for this application, per MPEP § 2733. Should the Office feel that a fee is required, the Commissioner is authorized to deduct the appropriate fee from Deposit Account 19-0134.

Respectfully submitted,

Novartis  
Corporate Intellectual Property  
One Health Plaza, Building 104  
East Hanover, NJ 07936-1080  
(862) 778-7922

  
\_\_\_\_\_  
David L. Marks  
Attorney for Applicants  
Reg. No. 37,881

Date: August 1, 2005

**Patent Term Adjustment Chart**

Event Description	Date of Event	Time Allowance	Met Time Frame? (Yes or No)		Adjustment - No. of Days	
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U.S. filing (after 5/28/00)	2/4/2001	_____				
Non-Substantive First OA	4/30/2001	_____				
Response to OA	8/30/2001	3 months from OA		no		31
First OA	6/27/2003	14 months from filing date	no		449	
Response to OA	8/26/2003	3 months from OA		yes		
Subsequent OA	10/1/2003	4 mo. from Response	yes			
Response to OA	12/15/2003	3 months from OA		yes		
Subsequent OA (Allowance)	3/24/2004	4 mo. from Response	yes			
Response to OA (RCE)	6/15/2004	3 months from OA		yes		
Subsequent OA		4 mo. from Response				
Response to OA		3 months from OA				
Notice of Allowance	6/6/2005	4 mo. from Response or 14 mos. from filing date if <u>first</u> substantive action	no		234	
(Drawings/312 Amendment/ Resp. to Examiners Reasons for Allowance/etc.)		See Footnote Below *				
Response from PTO (for 312 Amendment/Drawings/etc.)		See Footnote Below *				
Issue Fee Paid	8/1/2005	3 months from NOA		yes		
Issued		4 mo. from Issue Fee Paid				
		3 years from filing date**			***	***

**"Initial" PTA**

PTO Deficient = + 683 days

Novartis Deficient = - 31 days

Initial Adjustment = 652 days

**"Final" PTA**

PTO Deficient = + days

Novartis Deficient = - days

Final Adjustment = days

PTA PENALTY FOR FILING AFTER THE NOTICE OF ALLOWANCE: Drawings: 4 months (120 days) from date of their filing (even if requested by the Examiner) unless a response is received from the PTO 312 Amendments: penalty starts on the date the amendment is mailed and ends on the date of the Office Action/Notice in response or 4 months (120 days) whichever is shorter; response to Examiner's Reasons for Allowance and Request for PTA no reduction/penalty of time.

\* This calculation does not apply to applications with RCE's as they are not required to issue within 3 years. All other TA/PTE calculations are not affected.

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